

FREQUENTLY ASKED QUESTIONS REGARDING IMPLEMENTATION OF PAIN MANAGEMENT CLINIC REGULATION

Pursuant to T.C.A. § 63-1-301, a “**pain management clinic**” is defined as a privately-owned clinic, facility or office in which any health care provider licensed under Title 63 provides “chronic nonmalignant pain treatment”, meaning the prescribing of opioids, benzodiazepines, barbiturates, or carisoprodol for ninety (90) days or more in a twelve-month period, unrelated to cancer or palliative care, to a majority of its patients. For purposes of determining if a clinic should be licensed under this part, the entire clinic, facility, or office caseload of patients who received medical services from all medical doctors, osteopathic physicians, advanced practice registered nurses and physician assistants who serve in the clinic, facility or office shall be counted.

‘Pain management clinic’ shall **also** mean any privately-owned, facility or office which advertises in any medium for any type pain management services. Pursuant to T.C.A. § 63-1-301 et seq., all pain management clinics in Tennessee must be licensed by the Department of Health.

The following FAQ responses and statements do not supersede the terms of the Tennessee Code or the relevant rules and regulations, but are merely provided as guidance. They are provided in a good faith effort at transparency in the Department’s regulatory role. The questions are informational in nature and do not constitute legal advice. Moreover, the questions and answers are subject to change and the Department is not bound by this particular guidance in its interpretation of the law.

Those who are or may be subject to this regulation are strongly urged to review the applicable statutes and rules and seek their own legal counsel if necessary. Please note that practitioners are required to be in compliance with any changes in the law and that this may require continued vigilance.

- 1. Question:** With reference to the language in the definition of a ‘pain management clinic’ regarding the 90 days of prescriptions in a twelve-month period, does this only refer to 90 consecutive days of such prescriptions?

Answer: No. Treatment with one of the named substances for ninety (90) days within a twelve-month period, whether consecutive or not, rises to the level of prescribing outlined in T.C.A. § 63-1-301 et seq.

- 2. Question:** My clinic is associated with a hospital. Do I need to obtain a pain management clinic license?

Answer: Possibly. T.C.A. § 63-1-302 provides some exemptions from the requirement to obtain pain management clinic licensure, primarily for health care facilities otherwise inspected pursuant to T.C.A. Title 68. The Department encourages practitioners to seek guidance from their legal counsel as to whether their clinic qualifies for exemption under T.C.A. § 63-1-302.

3. **Question:** What is the penalty for operating or working in an unlicensed pain management clinic?

Answer: T.C.A. §63-1-311 provides that each practitioner providing pain management services, as well as anyone who owns or operates an unlicensed pain management clinic, is subject to an administrative penalty of not less than \$1,000 and not more than \$5,000 per day.

4. **Question:** Once my clinic obtains a pain management clinic license, can I move my clinic to a new address?

Answer: No. Because T.C.A. § 63-1-316(f) requires that each clinic location be licensed separately, regardless of whether that clinic is operated under the same name, ownership, or management as another clinic; it is not possible under the law to change the location or address of a clinic's license. Thus, a pain management clinic that moves from its original location, even if it is relocating nearby, is treated as a completely separate and new clinic under the law. If you operate a licensed pain management clinic and intend to open another clinic at a different location, you must first submit a separate application for the new location and obtain a new license prior to operating at the new location, regardless of whether or not you intend to continue to operate a clinic at the original location.

5. **Question:** If my business has more than one clinic location, does my medical director need to be physically present on-site for 20% of the operating hours of each location, or just 20% of the total operating hours?

Answer: Each location. T.C.A. § 63-1-309(c) requires the medical director to be on-site a minimum of 20% of each clinic's weekly total operating hours. Additionally, a medical director may not provide services at more than four (4) pain management clinics.

6. **Question:** Can my clinic split the medical director responsibilities among two or more qualified physicians?

Answer: No. Only one individual can be designated as a pain management clinic's medical director at any one time. While Tenn. Comp. R. & Regs. Rule 1200-34-01-

.10(1)(a)(6) requires that the clinic's medical director identify a pain management specialist who has agreed to provide coverage in the event the Medical Director is unable to fulfill his or her duties on a temporary basis. This coverage may only be provided on a temporary, short-term basis, and will not count against the four clinic limit at which one can serve as a medical director. If the Medical Director will not be able to return, your clinic must notify the Department of the identity of the new qualified interim medical director within 10 days on a form prescribed by the department with documentation that she or he is a pain management specialist serving as interim medical director. The clinic may operate under the direction of the interim medical director for a 30-day grace period, during which time the new, incoming medical director must submit a completed application for a new pain management clinic license at the clinic's location.

7. **Question:** I am also serving as a coverage medical director for another pain clinic (on a temporary, short-term basis, when the full-time medical director is unavailable due to illness or vacation). Does this count against the limit of four pain management clinics I can serve as medical director?

Answer: No. Tenn. Comp. Rule and Reg. 1200-34-01-.10(1)(a)(6.) provides that such temporary, short-term coverage service does not count against the limit of four pain management clinics that a medical director can serve.

8. **Question:** When does the medical director at my clinic need to become a pain management specialist?

Answer: Before you begin operating as a pain clinic. T.C.A. § 63-1-301(8) defines a pain management specialist as a Tennessee-licensed physician with an unencumbered license who has obtained accreditation and training along one of four recognized pathways. A pain management clinic cannot operate in Tennessee without a medical director who has met this requirement. The four recognized pathway requirements are as follows:

- (A) Has a subspecialty certification in pain medicine as accredited by the Accreditation Council for Graduate Medical Education (ACGME) through either the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA), or is eligible to sit for the board examination offered by ABMS or AOA, and maintains the minimum number of continuing medical education (CME) hours in pain management to satisfy retention of such certification;
- (B) Attains American Board of Pain Medicine (ABPM) diplomate status and maintains the minimum number of CME hours in pain management to satisfy retention of ABPM diplomate status;

- (C) Is board certified by the American Board of Interventional Pain Physicians (ABIPP) by passing parts 1 and 2 of its examination and maintains the minimum number of CME hours in pain management to satisfy retention of ABIPP diplomate status; or
- (D) Has an active pain management practice in a clinic accredited in outpatient interdisciplinary pain rehabilitation by the commission on accreditation of rehabilitation facilities or any successor organization.

9. Question: My clinic wishes to employ a medical director who does not yet meet the definition as a pain management specialist and one or more of the tests required to become qualified will not be offered for some time. Can this physician serve as medical director before sitting for the test?

Answer: No. Pursuant to T.C.A. § 63-1-301(4)(c), after July 1, 2016 a physician must meet the definition of a pain management specialist to be qualified to be a medical director. In order for your pain management clinic to operate legally, you will need to find and employ a physician who already meets all the statutory requirements. Additionally all collaborating and supervising physicians of advanced practice registered nurses and physician assistants, must also be pain management specialists.

10. Question: Is there a list available of the physicians qualified as pain management specialists in the state?

Answer: No. Medical licenses in Tennessee are issued by profession and not by specialty. The Department does not have a list of physicians qualified as pain management specialists.

11. Question: Does the provision of mental health treatment by mental health professionals fall within the ambit of Tenn. Code Ann. § 63-1-301(2) or the rules promulgated by the Department?

Answer: No. The use of benzodiazepines for treatment of mental health conditions (such as anxiety or depression) and not for pain management does not fall within the scope of Tenn. Code Ann. § 63-1-301(2), which specifically references "Chronic non-malignant pain treatment" services in the definition of "pain management clinic".

12. Question: If I prescribe Suboxone or buprenorphine for treatment of Substance Use Disorder (SUD) only, do I have to register as a pain clinic?

Answer: No. T.C.A. §53-11-311 permits the prescription of buprenorphine products only for patients undergoing opiate withdrawal treatment or for other FDA-approved purposes. Suboxone and buprenorphine are opioids and, if used in any form for purposes which include pain management, must be counted when determining whether a clinic requires registration as a pain clinic. However, if and only if these drugs are used in accordance with their FDA indication solely in the context of a bona fide program for Medication-Assisted Treatment (MAT) for opioid dependence, this would not be considered pain management services and those patients should not be counted as such. Finally, note that if a significant amount of your patient population is receiving MAT, your practice may need to register as a nonresidential office-based opiate treatment facility (OBOT), as defined at Tenn. Code Ann. § 33-2-402, with the Tennessee Department of Mental Health and Substance Abuse Services. Licensing procedures for OBOTs can be found at Tenn. Comp. Rule and Regs. 0940-05-35-.04.

- 13. Question:** Does the provision of pain management services in an oncological setting for the treatment of malignant conditions fall within the scope of T.C.A. §63-1-301 et seq. or the rules promulgated by the Department?

Answer: No. T.C.A. §63-1-301(2) defines chronic non-malignant pain treatment to be treatment for pain unrelated to cancer or palliative care.

- 14. Question:** Is Tramadol (Ultram) an opioid such that the prescribing of it should be counted for purposes of assessing whether a provider must register as a pain clinic?

Answer: Yes. Tramadol, which works on the brain's opioid receptors and is a Schedule IV controlled substance, has an approximate morphine equivalent dose value of 0.1 and should be considered in assessing whether a provider must register as a pain management clinic.

- 15. Question:** Is codeine considered an opioid?

Answer: Yes. Codeine has an approximate morphine equivalent dose value of 0.15, is a schedule II FDA controlled substance, and should be considered in assessing whether a provider must register as a pain management clinic.

- 16. Question:** Are cash-only or money-order payments permissible forms of payment for patients of pain management clinics?

Answer: Only as a co-pay. T.C.A. §63-1-310 specifically limits acceptable forms of payment for pain management clinics to checks or credit cards except that clinics may accept cash for a co-pay, coinsurance, or deductible when the remainder of the charge is submitted to the patient's insurance plan for reimbursement.

17. Question: My licensed pain management clinic no longer meets the definition of a pain clinic at T.C.A. §63-1-301(7). Am I still required to comply with the pain management clinic laws, rules, and regulations?

Answer: Yes. Any clinic, facility, or office which holds a pain management clinic license is subject to the pain management clinic laws for as long as it holds that license, regardless of whether that clinic, facility, or office still meets the definition of a pain management clinic. Tenn. Comp. Rule and Reg 1200-34-01-.07 allows a pain management clinic to voluntarily inactivate its license via an inactivation form issued by the Department, but unless and until the license is inactivated, your clinic must comply with all pain clinic laws and rules.

18. Question: Who holds the license for a pain management clinic?

Answer: Under the current law, pain management clinic licenses in Tennessee are granted to and held by each clinic's medical director. Pursuant to T.C.A. § 63-1-316(b)(2), a clinic granted a pain management clinic certificate prior to July 1, 2017, may continue operating under that certificate until it expires, and that certificate will be treated as a license until expiration. At least ninety days before a clinic operating under a previously-granted certificate nears that certificate's expiration date, the medical director must submit a completed application for a pain management clinic license as if the clinic were applying for an initial license.

19. Question: My clinic is operating under a pain management clinic certificate granted before July 1, 2017. When should I begin applying for a pain management clinic license?

Answer: You must submit a completed application for your pain clinic license at least 90 days before your pain management clinic certificate is due to expire.

20. Question: Can I open a pharmacy next door to my pain management clinic?

Answer: Tenn. Code Ann. § 63-1-316(h) mandates that owners of pain management clinics may not locate or participate in locating a pharmacy in which any owner of the pain management clinic has an ownership interest adjacent to the clinic. Tenn. Comp.

Rule and Reg. 1200-34-01-.01(2) defines “Adjacent” as “within 1,000 feet”. Violation of this law is grounds for revocation of the pain management clinic license.

21. Question: How many continuing education courses do I need if I work in a pain clinic?

Answer: In addition to any other continuing education requirement to maintain licensure under Title 63, Tenn. Comp. Rule and Reg. 1200-34-01-.11(2) requires that any practitioner providing services at a pain management clinic complete at least ten (10) hours of continuing education courses during their licensure renewal cycle in a topic related to pain medicine. Those topics are:

- (a) Prescribing controlled substances;
- (b) Drug screening or testing;
- (c) Pharmacological and non-pharmacological pain management;
- (d) Completing a pain management focused history and physical examination and maintaining appropriate progress notes;
- (e) Comorbidities with pain syndromes; and
- (f) Substance abuse and misuse including diversion, prevention of same, and risk assessment for abuse.

In addition, the clinic’s medical director, and all collaborating or supervising physicians of advanced practice registered nurses or physician assistants working in the clinic, must obtain the continuing education required to maintain certification, accreditation, and/or diplomate status in his or her pain management board or association to continue to qualify as a pain management specialist.

22. Question: What type of bonds and/or insurance does a physician need to have when operating a pain management clinic?

Answer: Tenn. Comp. Rule and Reg., Rule 1200-34-01-.15 requires that a licensed pain management clinic hold as surety either bonds or liability insurance in an amount equal to at least one year’s operating expense.

23. Question: How do I apply for a pain management clinic license?

Answer: An application can be obtained from the Department’s Administrative Office. Online applications may be available at: <https://lars.tn.gov/datamart/login.do;jsessionid=-NADnlKgrx+XystaF8tc9voe>

24. Question: What is the application fee for opening a pain management clinic?

Answer: \$1,500.00, as set forth by Tenn. Comp. Rule and Reg., Rule 1200-34-01-.06(1) plus the \$10 state regulatory fee.

25. Question: What is the inspection schedule and fee?

Answer: The inspection fee is \$1,500.00, as set forth by Tenn. Comp. Rule and Reg., Rule 1200-34-01-.06(4). Pursuant to rule 1200-34-01-.08, a clinic's initial inspection fee is due at the time of license application. For new licensees, the inspection shall be conducted within 90 business days of the Department's determination that an application is complete. If a clinic does not pass its initial inspection, the Department, at its discretion, may re-inspect the clinic subject to a \$1,000.00 re-inspection fee. Once a clinic is licensed, the department shall conduct biennial random inspections. The standard \$1,500.00 inspection fee is due 30 days following each biennial inspection.

26. Question: Can the medical director transfer his license to a new pain management specialist if he leaves our clinic?

Answer: No. Under T.C.A. § 63-1-316(f), a pain management clinic license is neither assignable nor transferable once granted. However, under Tenn. Comp. Rule and Reg., Rule 1200-34-01-.09(1), a clinic may continue to operate under the previous medical director's pain management clinic license for up to a thirty (30) day grace period, provided that the clinic informs the Department of its interim medical director on the prescribed form within ten (10) days of the date the current medical director no longer qualifies or departs. During this grace period, a new medical director must immediately submit a completed application for a new pain management clinic license for that location. In addition, both the pain management clinic license and the interim medical director are liable for any actions occurring at the pain management clinic during this time. Additionally should the current medical director inactivate the clinic's license, the clinic must immediately cease operation. Prior to inactivating the license, the medical director shall have the responsibility to notify all patients receiving care at the clinic and arrange for continuity of care.

27. Question: What if I cannot find a new medical director but my interim director is willing to stay on for a little while longer?

Answer: Under Tenn. Comp. Rule and Reg., Rule 1200-34-01-.09(1)(g), if the clinic cannot find a permanent new medical director during the grace period, the interim may apply for a pain management clinic license to be issued for a term of six (6) months.

28. Question: If my pain management certificate is expiring, and I submit a completed pain management clinic licensure application for the same location, but the Department does not come to inspect my clinic before the expiration of the certificate, do I have to shut my doors?

Answer: No. If you submit an application for licensure which is deemed completed ninety days prior to your certificate's expiration, and your licensure application is for the same location as your certificate, but the Department does not inspect your clinic prior to the certificate's expiration, you may continue operation. The Department may issue you a license and conduct the initial inspection after you are licensed.

29. Question: If I have a change in ownership, but the licensee, the Medical Director, does not change, what do I have to report to the Department?

Answer: The annual report from the Medical Director must list all owners and their percentage of interest in the clinic for each month of the preceding year. Additionally, on the renewal application, the Medical Director will have to attest that no owner has been convicted or, pleaded nolo contendere to, or received deferred adjudication for an offense that constitutes any felony or for an offense that constitutes a misdemeanor, the facts of which relate to the distribution of illegal prescription drugs or a controlled substance. Failure to disclose the requested information could result in disciplinary action against the pain management clinic license as well as the individual licenses of the Medical Director and the owner.

30. Question: Does everyone who works in my clinic have to submit a criminal background check as part of my licensure application?

Answer: No. The medical director, anyone with ownership interest, and each person who holds a DEA registration who will be providing services at the clinic must always submit a criminal background check as part of the licensure application process. Sometimes others must as well. Criminal background checks must also be submitted for any person working in the clinic—as an employee or contractor—who has clinical contact with patients, contact with onsite patient information or specimens, or who has management responsibilities, who has been convicted of a felony, or who is under indictment for an offense involving the sale, diversion, or dispensing of controlled substances, or who has ever been convicted of an offense involving the sale, diversion, or dispensing of controlled substances. It is the Medical Director's responsibility to make an appropriate inquiry regarding whether he or she needs to submit an employee or contractor's criminal background check. The Department has promulgated a form on the pain management clinic website to help facilitate medical directors in conducting this inquiry.

31. Question: As a Medical Director do I have to get re-fingerprinted again every two years?

Answer: No. A clinic's license will expire every two years. As part of the renewal process you will have to make several attestations that the owners, employees, and contractors working in your clinic don't have criminal backgrounds as outlined in the rules. This includes an attestation that no person working in the clinic—as an employee or contractor—who has clinical contact with patients, contact with onsite patient information or specimens, or who has management responsibilities, has been convicted of a felony, or is under indictment for an offence involving the sale, diversion, or dispensing of controlled substances, or has ever been convicted of an offense involving the sale, diversion, or dispensing of controlled substances. If anyone has, then the Department may require that person's criminal background check be submitted with the renewal application.

- 32. Question:** I am relocating my pain management clinic practice to a new location. I know that I have to apply for a new pain management clinic license for the new location, but I'm worried about the timing of closing my current practice and the inspection. What assurances can I obtain that I won't effectively be shut down while waiting to be inspected?

Answer: The Department recognizes that the need for an initial licensure inspection in the process of moving locations can raise concerns regarding patient continuity of care. Therefore, if a clinic wishes to move locations it may arrange with the Department to have its current pain management clinic inspected prior to moving, and should the pain clinic pass inspection and be otherwise qualified for licensure, the Department may issue a license to the new location which will be inspected after the license is issued, allowing the clinic more freedom to determine when its move will occur. The Department will charge a re-inspection fee for the inspection of the new clinic location once the move does occur.